201-15385

High Production Volume (HPV) Challenge Program

Data Analysis and Test Plan for

Resorcinol

CAS Number 108-46-3

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1. EXECUTIVE SUMMARY

INDSPEC is committed to fulfilling the High Production Volume (HPV) commitments it made under the United States Environmental Protection Program on February 14, 2001. As part of this commitment, INDSPEC has volunteered to assess the health and environmental hazards of Resorcinol.

INDSPEC has identified data from various sources, these include company proprietary files, peer-reviewed published literature, specific test reports and/or calculated endpoints using widely accepted computer-modelling programs.

Conclusions about the nature of Resorcinol gained from analysis of all available data are as follows:

HUMAN HEALTH

Resorcinol is classified as harmful if swallowed. Long term exposure gives a NOEL of 250 – 260 mg/kg in rats and mice. When adsorbed through the skin or the G.I. tract nearly all is excreted in urine in 24 hours. Repeated administration over 30 days does not lead to storage or accumulation in tissues.

In vitro mammalian cell assays with Resorcinol demonstrated gene and chromosome mutations. However *in vivo* tests did not show any signs of genotoxicity. Long-term animal studies were without findings to demonstrate that Resorcinol has any carcinogenic effect or developmental effects.

ENVIRONMENT

The lowest no effect concentration of Resorcinol is 172 µg a.i./l (NOEC, full life cycle toxicity test for Daphnia magna). Resorcinol is ready biodegradable and has a very low Pow value of 0.8, and so the potential for bioaccumulation is regarded as low. Fugacity modelling indicates that 99% of Resorcinol will partition to water. A calculated Henry's constant indicates that resorcinol can be described as extensively non-volatile from water. So it can be assumed that the compound remains in water phase when discharged to the environment.

Physicochemical data, environmental fate data, ecotoxicity data and mammalian toxicity data endpoints for Resorcinol are fulfilled by using existing measured data or data calculated by the EPIWIN computer model with the exception of toxicity to fertility data. To address this data gap a study is currently being conducted with results due early 2005. No further testing is proposed for this program.

Table 1. Matrix of Available and Adequate Data for Resorcinol for SIDS endpoints

HPV Data Category	**Test Endpoint**	**Available Data (Klimish Score)**	**Testing Planned**
Physical and Chemical Data	Melting Point	Y (1)	N
	Boiling Point	Y(1)	N
	Vapor Pressure	Y(1)	N
	Partition Coefficient	Y(2)	N
	Water Solubility	Y(1)	N
Environmental Fate and Pathways	Photodegradation	Y(2)	N
	Stability in Water (Hydrolysis)	Y(2)	N
	Transport/Distribution	Y(2)	N
	Biodegradation	Y(2)	N
Ecotoxicity	Acute/Prolonged Toxicity to Fish	Y(2)	N
	Acute/Prolonged Toxicity to Aquatic Invertebrates (Daphnia)	Y(1)	N
	Acute Toxicity to Aquatic Plants (Algae)	Y(2)	N
Toxicity	Acute Toxicity (Oral)	Y(2)	N
	Acute Toxicity (Dermal)	Y(2)	N
	Repeated Dose	Y(1)	N
	Genetic Toxicity *in vitro* –	Y(1)	N
	Genetic Toxicity – *in vivo*	Y(1)	N
	Reproductive Toxicity	N	Y
	Developmental Toxicity	Y(2)	N

2. GENERAL SUBSTANCE INFORMATION

Resorcinol is manufactured by INDSPEC Chemical Corp. at Petrolia, Pennsylvania. The process is based on the sulfonation of benzene under conditions that promote di-substitution in the meta position, followed by fusion with anhydrous caustic. The product is purified under conditions to yield a technical grade product, typically 99.8% pure.

Resorcinol is a crystalline, aromatic chemical that is water soluble and very conductive to derivitization. Important reactions of resorcinol are: alkylation, acylation, amination,carboxylation, condensation and aldehydes and ketones, coupling with arylamines, etherification, halogenation, nitration and sulfonation.

Resorcinol is the essential component of an adhesive system used in the manufacture of tires for passenger cars, trucks, off-the–road equipment and other fibre reinforced rubber mechanical goods. Polyester, nylon, aramid, rayon and glass tires cords are treated with an aqueous adhesive containing resorcinol, formaldehyde and synthetic rubber latex. In addition to excellent adhesion, the attributes of the water based adhesive system are its ease of preparation, latitude of composition and low level of toxicity. Resorcinol and a methylene donor are also compounded into carcass skim stocks to enhance the adhesion of rubber to RFL treated tire cords. Dry bonding agents based on Resorcinol or resorcinol-formaldehyde resins have found world-wide acceptance as the adhesive system for bonding brass plated steel tire cords in radial tires.

Adhesives formulated from resorcinol-formaldehyde resins or phenol modified resorcinol-formaldehyde resins are the criteria for wood bonding applications demanding room temperature cure, structural integrity, and water proof characteristics. These adhesives retain their strength at temperatures approaching the charring point of wood and are not affected by exposure to the cryogenic temperatures of liquefied natural gas.

Resorcinol is an important chemical intermediate in the manufacture of speciality chemicals, such as light screening agents for the protection of plastics from exposure to ultraviolet light. Other uses include the manufacture of dye-stuffs, pharmaceuticals, flame retardants, agricultural chemicals, fungicidal creams and lotions, explosive primers, antioxidants, a chain extender for urethane elastomers and a treatment to improve mechanical and chemical resistance of paper machine fabrics.

3. PHYSICOCHEMICAL PROPERTIES

See IUCLID section 2 for more detailed summaries

Table 2. Physicochemical Data

End point	Reference Number	Result
Melting Point	33 [m]	109-111°C
Boiling Point	33 [m]	280°C
	41 [m]	276.7° C
Vapor Pressure	41 [c]	0.011 mm Hg (0.1463 hPa) @ 25°C
	3 [m]	0.000203 mm Hg (0.00027 hPa) @ 25°C
Kow Partition Coefficient	41 [c]	1.03
	3 [m]	0.80
Water Solubility	41 [c]	8.571E+004 g/l @ 25°C
	32 [m]	1.11E+007 mg/l @20°C

[m] Measured value
[c] Calculated value

Physicochemical Summary:

The physical chemical data for Resorcinol are summarised in Table 2. These values were experimentally confirmed or obtained from the well-established and scientifically accepted reference handbook the Merck Index (O'Neil, 2001) as well as EPIWIN-calculated values (USEPA and Syracuse Research Corporation, 2000).

SUMMARY:

Adequate data (Klimish code 1or 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program (see Table 2 and IUCLID documents)

4. EVALUATION OF ENVIRONMENTAL FATE DATA

See IUCLID section 3 for detailed summaries

The data for each SIDS endpoint has either been experimentally confirmed or obtained from the well-established and scientifically accepted reference handbook the Merck Index (O'Neil,

2001) as well as EPIWIN-calculated values (USEPA and Syracuse Research Corporation, 2000).

4.1 Photodegradation

Table 3. Environmental Fate Data

Photodegradation						
	Direct Photolysis		Indirect photolysis			
Endpoint	Result	Ref	Result	Ref	Result	Ref
OH Rate Constant	-	12 [m]	2E-11 cm^3/ molecule-sec	12 [c]	2.0028E-10 cm^3/ molecule-sec	42 [c]
OH half life	100 hours		1.9 hours		0.64 hours (38 .452 min)	

[m] Measured value
[c] Calculated value

Direct photolysis value was determined experimentally, and values for photodegradation and atmospheric oxidation were calculated based upon chemical structures using EPIWIN and are shown in Table 3.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

4.2 Hydrolysis

Resorcinol does not possess any functional groups that are regarded as being susceptible to hydrolysis under environmental conditions (Lyman, W.J., Reehl, W.F. and Rosenblatt, D.H., Handbook of Chemical Property Calculation Methods, McGraw-Hill, Inc., Washington, 1990, pages 7-4 and 7-5).

The software prediction programme HYDROWIN v1.66 predicts that resorcinol will be stable to hydrolysis. The model cannot estimate hydrolysis rate constants due to the absence of any hydrolysable groups.

4.3 Chemical Transport and Distribution in the Environment

Table 4. Transport between environmental compartments Data

Transport/Distribution	Reference	Results
Fugacity Level 1	27 [c]	Air =0.0% Water =99.88% Soil=0.06% Sediment=0.07%
Estimated Koc	27 [c]	2.94 (soil and sediment)

[c] Calculated value

These results demonstrate that resorcinol partitions primarily into water largely due to its high water solubility.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

4.4 Biodegradation and Bioaccumulation

Resorcinol was tested in a ready biodegradation assay and an inherently biodegradation assay. These studies were conducted to the accepted OECD guideline standards and clearly demonstrate that Resorcinol is biodegradable. Both results can therefore be regarded as reliable with out restrictions and fulfil the HPV SIDS endpoints.

Other studies conducted in aquatic media with isolated bacteria and fungal strains or with mixed cultures of activated sludge, digested sludge and soil confirm that resorcinol is biodegradable under aerobic and anaerobic conditions

A calculated value for bioconcentration factor has also been determined as below.

Table 5. Bioaccumulation

Bioaccumulation	Reference	Results
Estimated BCF	42 [c]	3.162

[c] Calculated value

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

Environmental Fate Summary:

Adequate data (Klimish code 1 or 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program

5. ECOTOXICITY DATA

See IUCLID section 4 for detailed summaries

Acute and prolonged toxicity to fish

Many studies have been conducted, by various authors, but none to recommended guidelines. However all the studies demonstrate that Resorcinol is toxic to fish in varying degrees (see Table 6 for a summary).

Table 6. Summary of available fish toxicity data

Species	Duration	Effect	Concentration (mg/l)	Test system	Reference
Leuciscus idus (Golden Orfe)	48h	LC50	38.4	Static	23
		NOEC	25		
	96h	LC50	34.7		
		NOEC	25		
Pimephales promelas	96h	LC50	53.4	Static	2
(Fat head minnow)	96h	LC50	26.8-29.5	Flow through	15
Gambusia affinis (mosquito fish)	96h	LC50	179.56-182.47	Static	28
Brachydanio rerio (Zebra fish)	7 days	LOEC (weight)	32	Semi-static	45
		EC50 (malformations)	54.8		
		LC50 (embryo lethality)	262		
Salmo gairdneri (salmon)	60 days	LC50 (embryo lethality)	320	Semi-static	45
		EC50 (malformations)	260		

With this weight of evidence it is therefore proposed that adequate data (Klimish code 2) are available for this endpoint, so no additional testing is proposed for the USEPA HPV Challenge Program

Acute and chronic toxicity to aquatic invertebrates

A concentration-time dependency was shown by experimental results obtained under static conditions for the grass shrimp (Palaemonetes pugio) which lives in salt water. (Reference No. 2)

Table 7. Chronic and acute toxicity data to Daphnia magna

Test Duration (hours)	Result (mg/l)	Reference
24	EC50= 107.6	10
48	EC50<0.8	7
48	LC50 = 1.28	19
96	LC50 = 0.25	13
Chronic Toxicity		
48	EC50>172 µg/l NOEC=172 µg/l	31
21 days	EC50>172 µg/l NOEC=172 µg/l LOEC>172 µg/l	31

There are many tests on the acute toxicity to water fleas (Daphnia magna) that have been conducted by various authors but not to any standardised guidelines (reference 7,10,13,19) (see Table 7). The general conclusion is that harmful affects may be dependent on duration of exposure and the trail conditions concerned. As these studies did not give a clear result a chronic toxicity to Daphnia Magna to OECD guidelines was conducted (reference 31). This study demonstrated that concentrations up to 172 µg a.i./l of Resorcinol had no adverse effects on survival, growth or reproduction of Daphnia magna. LOEC was determined to be >172µg a.i./l. This study clearly demonstrates that Resorcinol is very toxic to aquatic organisms, and so must be classified R50. This study can also be used to provide data for the acute toxicity endpoint as observations were made for mortality and effects on a daily basis for 21 days. After 48 hours EC>172 µg/l and NOEC = 172 µg/l.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

Toxicity to aquatic plants e.g. algae

In a cell-multiplication inhibition test performed on the green alga Chlorella pyrenoidosa, various chemicals were tested at one concentration each. At a concentration of 1.1 mg/l resorcinol, there was no observed cell-multiplication inhibition after 72 hours (reference no. 38).

In an experiment to determine growth inhibition EC50 values of 165.2 mg/l and 143.1 mg/l were determined for common duckweed (Lemna minor, exposure period 12 days) and Canadian pondweed (Elodea canadensis, exposure period 9 days)(reference no. 40).

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

Ecotoxicity Summary:

Adequate data (Klimish 1 or 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program.

6. MAMMALIAN TOXICITY

See IUCLID section 5 for detailed summaries

Many studies have been conducted, by various authors, but not all to recommended guidelines. Results of these studies have been summarised in Table 8.

Table 8. Summary of available Mammalian Toxicity Data

	Dose/result	**Remarks**	**Reference**
Acute Toxicity			
Acute Oral toxicity	LD50=202 mg/kg bw LD50=980 mg/kg bw LD50=301mg/kg	Harmful if swallowed	21 36 26
Acute Dermal toxicity	Rabbit LD50=3360 mg/kg bw (LD50 24 hour contact, intact and abraded skin)	Not classified	36
Repeated Dose			
Gavage rats 14 days	27.5-450 mg/kg bw/day NOEL 450 mg/kg./day	No toxic effects	1 and 32
Gavage mice 14 days	37.5-600 mg/kg/day NOEL 100 mg/kg/day	Fatalities in 300 and 600 mg/kg group. Dose group 100 mg/kg and below free from findings	
Gavage rats 90 days	32-520 mg/kg/day / NOEL=260 mg/kg	Not classified	1 and 32
Gavage mice 90 days	28-420 mg/kg/day / NOEL=225 mg/kg		
Inhalation-Rats 14 days	34mg/m^3 6 hours a day Other species tested were mice and guinea pigs	No evidence of toxic effects to lungs and trachea.	14

	Dose/result	Remarks	Reference
Genetic Toxicity *in vitro* –	Bacterial mutation assay (Ames test)	Negative	1 and 32
	Mammalian cell mutation (mouse lymphoma)	Positive (without S-9 mix)	
	Cytogenetic Assay (CHO cells)	Positive (with S-9 mix)	
	Sister chromatid exchange assay (CHO cells)	Positive	
	Unscheduled DNA synthesis (rat hepatocytes)	Negative	35
Genetic Toxicity – *in vivo*	Micronucleus assay	Negative	16
	SLRL Drosophila test	Negative	32
	Sperm abnormality	Negative	46
Toxicity to fertility	No data available	Study ongoing	
Developmental Toxicity/ Teratogenicity	Rat, Day 1-19 of gestation, 2ml/kg	No evidence of foetotoxic, embryotoxic or teratogenic effects following oral administration in any test	8
	Rat, Day 6-15 of gestation, 40-250 mg/kg		18
	Rat, Day 6-15 of gestation, 125-500 mg/kg		11
	Rabbit, Day 6-18 of gestation, 25-100 mg/kg		18
	Rabbit, Day 6-15 of gestation, 40-250 mg/kg		37
	Hen chick eggs, single dose, 99-804 mg/chick egg		29

6.1 Acute Toxicity

Three studies have been conducted as summarised in Table 8. Although none were conducted to the recommended guideline, all give comparable results that indicate the substance requires classification that the substance is harmful if swallowed (R22). Therefore it is considered that the data requirements have been met for this SIDS endpoint. It is therefore considered that there is sufficient data to cover this end point.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

6.2 Repeated Dose Toxicity

Toxicity studies were conducted by administering Resorcinol (>99% pure) in water by gavage to groups of F344/N rats and B6C3F1 mice for each sex for 14 days and 90 days. These studies form part of NTP Technical Report on the Toxicology and Carcinogenesis studies of Resorcinol and are therefore considered valid without restriction (reference 32). No chemical-related gross or microscopic lesions were observed in either study.

These results are regarded as sufficient for USEPA HPV Challenge Program, and no further testing is warranted.

6.3 Genetic Toxicity/Mutagenicity

Many studies have been conducted over the years (see IUCLID for full details). Genetic toxicology studies that were conducted as part of NTP Technical Report on the Toxicology and Carcinogenesis studies of Resorcinol confirmed the results of these studies (see Table 8). The general conclusions were that resorcinol is not a gene mutagen in bacteria or *Drosophila*, but was reported to induce mutation and chromosomal damage in mammalian cells *in vitro*. The *in vivo* mutagencity test data (also conducted for NTP report), however, did not reveal signs of genetoxic effects.

Adequate data (Klimish 1 and 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program

6.4 Reproductive Toxicity

No suitable data is available to address this end point. A drinking water two –generation reproductive study of resorcinol in rats is currently being conducted to U.S. EPA and OECD guidelines to fulfil this SIDS endpoint.

6.5 Developmental Toxicity

Several teratogenicity studies on rats and rabbits revealed no evidence of foetotoxic, embryotoxic or teratogenic effects following oral administration (reference 8, 11, 18, 29 and 37).

Adequate data (Klimish 2) are available for all endpoints, so no additional testing is proposed for the USEPA HPV Challenge Program

Mammalian Toxicity Summary:

With this weight of evidence it is therefore proposed that adequate data (Klimish code 1 or 2) are available for all endpoints, except toxicity to fertility. Additional testing is proposed for the USEPA HPV Challenge Program to address this data gap.

7. "BEYOND SIDS" ENDPOINTS

In addition to the studies to demonstrate effects of resorcinol on skin (reference 36) and eye irritation (reference 6) and skin sensitisation (reference 24) and carcinogenicity studies have been conducted.

Long-term gavage studies performed on rats and mice did not reveal any signs of carcinogenicity (reference 1). Nor did dermal treatment of rabbits (twice a week for 180 weeks) (reference 39), yield a higher incidence of local or systemic tumours.

Tumour initiation and promotion trails performed on mice (reference 4 and 45), rats (reference 20 and 47) and hamsters (reference 30) seem to indicate that resorcinol has a minor promotional effect and epithelial-proliferation properties.

Table 9. Summary of non SIDS acute Mammalian Toxicity Data

	Dose/result	Remarks	Reference
Skin irritation NOT SIDS ENDPOINT	500mg Corrosive	In-vivo design	36
	500mg Irritating		16
	500mg Irritating		22
Eye irritation NOT SIDS ENDPOINT	0.1ml of a 2.5% solution for 72 hours-Irritating		36
	0.1ml for 24 hours Irritating		22
Skin sensitization NOT SIDS ENDPOINT	Sensitizing	Maximisation design	24

8. CONCLUSIONS

As discussed above it is concluded that there are sufficient, reliable data on resorcinol for nearly all the SIDS endpoints following a thorough review of company proprietary files, peer-reviewed literature, and/or calculations using widely accepted computer modelling programs.

Test Plan Summary: Additional testing with resorcinol is proposed and currently underway to fulfil the following endpoint:

Toxicity to reproduction (OECD 416)

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ABBREVIATIONS

BCF	predicted bioconcentration factor
cm^3	centimetre cubed
HPV	High Production Volume
IUCLID	International Uniform Chemical Information Database
K_{oc}	organic carbon partition coefficients
LC_{50}	lethal concentration (to 50% of dosed animals)
LD_{50}	lethal dose (to 50% of dosed animals)
LOAEL	lowest observed adverse effect level
mg/kg	milligrams per kilogram
mg/L	milligrams per Litre
mmHg	millimetre mercury
NOAEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
QSAR	Qualitative Structure Activity Relationship
SIDS	Screening Information Data Set
USEPA	United States Environmental Protection Agency
USFDA	United Stated Food and Drug Administration